



12-13-0 AP15 Rec'd PCT/PTO 12 DEC 2006

Docket No. DRF 3.3-054

### CERTIFICATION UNDER 37 CFR 1.10

The undersigned hereby certifies that this correspondence, and all documents referred to as being enclosed herewith, is being deposited with the United States Postal Service on this date December 12, 2006 in an envelope as "Express Mail Post Office to Addressee," Mailing Label Number EV 504212874 US, addressed to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

  
Joan Anisiewski

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:  
**Karsten WASSERMANN, et al.**

Group Art Unit: **1614**

Examiner: **Zhang, Nancy L.**

Application No.: **10/561,639**

Filed: **December 20, 2005**

For: **COMPOSITIONS COMPRISING BALAGLITAZONE AND FURTHER  
ANTIDIABETIC COMPOUNDS**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

### INFORMATION DISCLOSURE STATEMENT

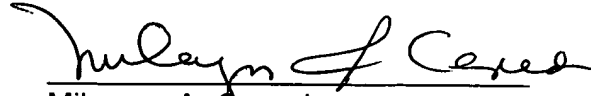
Pursuant to the duty of disclosure under 37 C.F.R. § 1.56, it is requested that the documents listed on the accompanying Form PTO/SB/08a be considered and made of record in the above-identified patent application. Required copies of these documents are enclosed.

No fee is believed to be due because this Information Disclosure Statement is being submitted prior to the mailing of a first Office Action on the merits. However, the Commissioner is authorized to charge our **Deposit Account No. 50-3221** for the required amount in the event that a fee is now due.

Respectfully submitted,

Dated: December 11, 2006

By:



Milagros A. Cepeda

Reg. No.: 33,365

Attorney for Applicant

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Bridgewater, NJ 08807  
FAX: (908) 203-6515

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10561639
Filing Date	2005-12-20
First Named Inventor	Karsten WASSERMANN
Art Unit	1614
Examiner Name	Zhang, Nancy L.
Attorney Docket Number	DRF 3.3-054

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

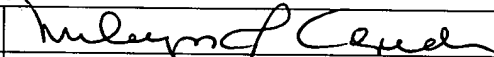
☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature		Date (YYYY-MM-DD)	2006-12-11
Name/Print	Milagros A. Cepeda	Registration Number	33,365

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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	Examiner Name	Zhang, Nancy L.	
	Attorney Docket Number	DRF 3.3-054	

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	6133293		2000-10-17	Ikeda, et al.	
	2	6150383		2000-11-21	Ikeda, et al.	
	3	6153632		2000-11-28	Rieveley	
	4	6156773		2000-12-05	Ikeda, et al.	
	5	6169099	B1	2001-01-02	Ikeda, et al.	
	6	6172089	B1	2001-01-09	Ikeda, et al.	
	7	6211205	B1	2001-04-03	Ikeda, et al.	
	8	6211206	B1	2001-04-03	Ikeda, et al.	

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	9	6211207	B1	2001-04-03	Ikeda, et al.	
	10	6214848	B1	2001-04-10	Ikeda, et al.	
	11	6218409	B1	2001-04-17	Ikeda, et al.	
	12	6232330	B1	2001-05-15	Ikeda, et al.	
	13	6239153	B1	2001-05-29	Ikeda, et al.	
	14	6251924	B1	2001-06-26	Ikeda, et al.	
	15	6274605	B1	2001-08-14	Ikeda, et al.	
	16	6277869	B1	2001-08-21	Ikeda, et al.	
	17	6288090	B1	2001-09-11	Ikeda, et al.	
	18	6303640	B1	2001-10-16	Ikeda, et al.	
	19	6323225	B1	2001-11-27	Ikeda, et al.	

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**U.S. PATENT APPLICATION PUBLICATIONS**

Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1					

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**FOREIGN PATENT DOCUMENTS**

Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup>	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	1	97/10819	WO	A1	1997-03-27	Ligand Pharmaceuticals, Inc.		<input type="checkbox"/>
	2	97/37688	WO	A2	1997-10-16	Takeda Chemical Industries, Ltd.		<input type="checkbox"/>
	3	97/41097	WO	A2	1997-11-06	Dr. Reddy's Research Foundation, et al.		<input type="checkbox"/>
	4	98/36755	WO	A1	1998-08-27	Warner Lambert Co.		<input type="checkbox"/>
	5	98/57635	WO	A1	1998-12-23	Smithkline Beecham PLC		<input type="checkbox"/>
	6	00/00195	WO	A1	2000-01-06	Takeda Chemical Industries, Ltd.		<input type="checkbox"/>

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	7	00/27434	WO	A1	2000-05-18	Smithkline Beecham PLC		<input type="checkbox"/>
	8	00/38666	WO	A2	2000-07-06	Metabasis Therapeutics, Inc.		<input type="checkbox"/>
	9	00/45818	WO	A1	2000-08-10	Astrazeneca UK Limited		<input type="checkbox"/>
	10	00/78333	WO	A2	2000-12-28	Eli Lilly and Company		<input type="checkbox"/>
	11	01/03659	WO	A1	2001-01-18	The Salk Institute for Biological Studies		<input type="checkbox"/>
	12	01/32158	WO	A2	2001-05-10	Bristol-Myers Squibb Company		<input type="checkbox"/>
	13	01/52825	WO	A2	2001-07-26	Novartis AG		<input type="checkbox"/>
	14	02/080936	WO	A1	2002-10-17	Ortho McNeil Pharmaceutical, Inc.		<input type="checkbox"/>
	15	02/13864	WO	A1	2002-02-21	Sankyo Company Limited		<input type="checkbox"/>
	16	02/058732	WO	A2	2002-08-01	Schering Corporation		<input type="checkbox"/>
	17	02/072069	WO	A1	2002-09-19	Novo Nordisk A/S		<input type="checkbox"/>

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	Attorney Docket Number	DRF 3.3-054		

	18	02/072146	WO	A2	2002-09-19	Novartis-Erfindungen Verwaltungsgesellschaft MBH	<input type="checkbox"/>
	19						<input type="checkbox"/>

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#### NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	1	PAUL, MARTIN: "Modes of Action and Clinical Efficacy of Pioglitazone as a New Principle for the Treatment of Type 2 Diabetes," Arzneimittel-Forschung, Vol. 49, No. 10 (1999), pp. 835-842.	<input type="checkbox"/>
	2	REASNER, C. A., II: "Promising new approaches," DIABETES, OBESITY AND METABOLISM, Vol. 1, (Suppl. 1) (1999), pp. S41-S48	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

#### EXAMINER SIGNATURE

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.